REMARKS

The status of the claims is as follows:

Original:	8 and 10-16
Currently amended:	1, 3, 9, 26, 30, 33-35, 37 and 39-41
Previously presented:	2, 4-7, 27-29, 31, 32, 38 and 42-44
Canceled:	17-25 and 36
New:	45-47

Claims 24, 25 and 36 are being canceled in this amendment. Claims 17-23 were canceled previously. Claims 1-16, 26-35 and 37-47 are pending with entry of this amendment.

Claims 1, 9, 26, 30, 37 and 41 have been amended herein to replace the term "filler/disintegrant" with the term "filler". The references to disintegrants (v. superdisintegrants) have been removed from claim 3, which indirectly depends from claim 1, in order to conform its language to that of claim 1 as amended herein. The foregoing amendments are discussed below in the remarks on the section 103 rejection.

The recitation of claims 34 and 35 has been incorporated into claim 33, and claims 34 and 35 have been amended to recite that efavirenz is present in amounts of 300 mg and 600 mg respectively.

Claims 39, 40 and 41 have been amended to depend from claim 38 instead of claim 37. Claim 41 has been further amended to recite the solvent.

New claim 45 recites that the efavirenz in the tablet of claim 38 is crystalline. New claims 46 and 47 recite that the efavirenz in the tablet of claim 41 is present in amounts of 300 mg and 600 mg respectively.

The claim amendments set forth above are similar to previous claim amendments and in the same or similar manner are fully supported by the application as originally filed. None introduces new matter.

Information Disclosure Statement

Attached hereto as Exhibit 1 is a copy of the information disclosure statement submitted on November 10, 2003, along with a copy of the post card showing receipt of the statement by the Patent Office. Copies of the cited references (not enclosed herewith) were sent with the statement. The Examiner is asked to consider the references cited in the statement, make them of record, and return an initialed copy of the statement with the next communication to

Applicants. If any of the cited references are missing from the file, the Examiner is asked to contact the undersigned to obtain fresh copies.

Rejection under 35 U.S.C. § 103

Claims 1-15 and 24-44 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Makooi in view of Remington. Claims 24, 25 and 36 have been canceled, rendering the rejection moot as applied thereto. This rejection is traversed with respect to claims 1-15, 26-35 and 37-44 and with respect to new claims 45-47.

For the reasons given in the response filed October 6, 2003 and incorporated by reference herein, it is Applicants' position that Makooi does not teach or suggest the use of a low level of superdisintegrant in efavirenz formulations, whether considered alone or in view of Remington. Quite the contrary, Makooi in view of Remington directs the person of ordinary skill in the art to employ 10% or more superdisintegrant.

The Examiner has admitted that Makooi does not teach a 1-5% superdisintegrant concentration, but has asserted that the distinction between the instant claims and Makooi is illusory in that the claimed tablets must contain both disintegrant and superdisintegrant and that no distinction is drawn between disintegrants and superdisintegrants in the subject application. The Examiner overstates the case. Before the amendment herein, the claimed tablets could contain either a disintegrant and a superdisintegrant or a filler and a superdisintegrant. The claims have been amended herein to remove the disintegrant option by replacing the term "disintegrant/filler" with the term "filler". Accordingly, the claims as amended herein require a superdisintegrant but do not require a separate disintegrant. Furthermore, the subject application does draw a distinction between superdisintegrants and disintegrants. Lines 8-13 on page 3 provide a list of disintegrants. Lines 24-27 on page 3 subsequently state that certain of the disintegrants listed above at lines 8-13 are superdisintegrants; i.e., of the disintegrants listed at lines 8-13 the following are superdisintegrants: carboxymethylcellulose sodium, croscarmellose sodium povidone, guar gum, polacrilin potassium, and pregelatinized starch. In other words, page 3 indicates that superdisintegrants represent a particular sub-class of disintegrants. Claim 3 has been amended to recite only the foregoing superdisintegrants.

In view of the claim amendments removing the references to disintegrants and in view of the remarks set forth in the preceding paragraph, it is clear that the distinction between the instant claims and Makooi is real, not illusory. Accordingly, Makooi in view of Remington does not render the claimed invention prima facie obvious, and withdrawal of the section 103 rejection is accordingly requested.

Declaration under 37 C.F.R. 1.132

The Examiner has asserted that the Rule 132 Declaration is sufficient to overcome the rejection of claim 16 but is not commensurate in scope with the other claims. Claim 16 recites a tablet composition containing specific ingredients in specific amounts, and corresponds to one of the tablet compositions used in the experiments described in the Declaration. This is an unduly narrow application of the showing provided by the Declaration. It is Applicants' position that the evidence of unexpected results provided in the Declaration can be extrapolated to and is representative of the entire class of tablets embraced by the claims as amended herein. The Declaration shows that efavirenz tablets containing 5 wt.% or less of superdisintegrant unexpectedly have better bioavailability than comparable tablets having more than 10 wt.% superdisintegrant and unexpectedly have comparable or better bioavailability than commercial capsules. This showing supports the patentability of all of the claims in that each claim requires a superdisintegrant concentration of less than 5% in the tablet.

As stated in the response filed October 6, 2003, evidence of unexpected results is not required to overcome this obviousness rejection, because the cited references do not render the claimed invention prima facie obvious. However, assuming strictly for the sake of argument that the claims were prima facie obvious, the showing in the Declaration rebuts the prima facie case as applied to all of the claims as amended herein.

Claim Objection

Claim 16 has been objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form. The Examiner's invitation to rewrite the claim in independent form is declined, because it is believed that the rejection of the base claim should be withdrawn for the reasons set forth above. Withdrawal of the objection is accordingly requested.

The application is believed to be in condition for allowance and passage to issue is requested. The Examiner is invited to telephone the undersigned should any minor matters need to be resolved before a Notice of Allowance can be mailed.

Respectfully submitted,

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